K070911

1 of 1

Section 5 – 510(k) Summary

AUG 10 2007

General Information

Owner's Name:	STD Med., Inc.
Address:	75 Mill Street Stoughton, Massachusetts 02072
Telephone Number:	(781)828-4400
Fax Number:	(781)344-5895
Contact Person:	Mark Orphanos
Subject Device Name:	STD Med Primo Port
Trade Name:	Primo Port
Common/Usual Name:	Titanium Subcutaneous Port & Catheter
Classification Name:	LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II
Predicate Device Name:	BardPort® Implanted Port
Trade Name:	Titanium Port, Titanium Low-Profile Port
Common/Usual Name:	Titanium Subcutaneous Port & Catheter
Classification Name:	LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II
Premarket Notification:	K050310, concurrence date – April 18, 2005

Device Description

The STD Med Primo Port kit contains 1 Titanium port, 1 catheter of choice, and 2 corresponding catheter locks. The catheter is introduced into the vascular system and attached to the port stem using a catheter lock. The port is then sutured under the skin in area of the subclavian fossa. The port is accessed percutaneously using a non-coring needle that penetrates a silicone rubber septum at the top of the port. The port system is the mechanism with which fluids can pass into and out of the central venous system.

Intended Use

The STD Med Primo Port is a totally-implantable vascular access device designed to provide long term, repeated access to the vascular system.

Performance Testing

Performance data demonstrated that the STD Med Primo Port is substantially equivalent to the predicate device and/or met pre-determined acceptance criteria. The risks associated with use of the new device were found acceptable when evaluated by FMEA.

Bench tests performed in accordance with FDA's October 1990 *Guidance on 510(k) Submission for Implanted Infusion Ports* included assessments of overall dimensions, septum durability, port leakage, fluid dynamics clearance, catheter-to-port connection, flow rate, obturation, priming volume, needle insertion & retention forces and stem strength.

No biocompatibility testing was conducted; all materials used in the manufacture of the Primo Port device have been previously cleared for similar devices.

Conclusion

The Primo Port meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the Primo Port is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2007

STD Med., Incorporated
C/O Pamela Papineau, RAC
President
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K070911
Trade/Device Name: STD Med Primo Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: July 20, 2007
Received: July 23, 2007

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

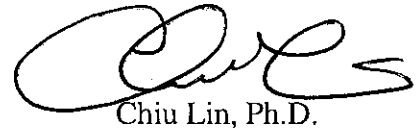
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K070911

Device Name: STD Med Primo Port

Indications for Use:

The STD Med Primo Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

Prescription Use __X___ OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ADE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k070911